UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

CLERK, U. S. DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
FILED 8/18/11
, CLERK
BY DEPUTY

UNITED STATES OF AMERICA	§	
	§	
v.	§	**CRIMINAL NO. H-11-535**
	§	
FREDDA BRANYON	§	

PLEA AGREEMENT

The United States of America, by and through José Angel Moreno, United States Attorney for the Southern District of Texas and Samuel J. Louis, Assistant United States Attorney, and the defendant, Fredda Branyon and the defendant's counsel, pursuant to Rule **11(c)(1)(A)** of the Federal Rules of Criminal Procedure, state that they have entered into an agreement, the terms and conditions of which are as follows:

The Defendant's Agreement

1. The defendant agrees to plead guilty to Count Twelve of the Criminal Information. Count Twelve charges the defendant with the Introduction of an Unapproved New Drug into interstate commerce in violation of Title 21, United States Code, Section 331(d). The defendant, by entering this plea agrees that she is waiving any right to have the facts that the law makes essential to the punishment either charged in the criminal information, or proved to a jury or proven beyond a reasonable doubt.

Punishment Range

2. The statutory maximum penalty for a violation of Title 18, United States Code, Section 371 is up to three (3) years imprisonment and a fine of up to $10,000. Additionally, the defendant may receive a term of supervised release after imprisonment of not more than one (1) year. Defendant acknowledges and understands that if she should violate the conditions of any period of supervised release which may be imposed as part of her sentence, then defendant may be imprisoned for the entire term of supervised release, without credit for time already served on the term of supervised release prior to such violation. Defendant understands that she cannot have the imposition or execution of the sentence suspended, nor is she eligible for parole.

Mandatory Special Assessment

3. Pursuant to Title 18, U.S.C. § 3013(a)(2)(A), immediately after sentencing, defendant will pay to the Clerk of the United States District Court a special assessment in the amount of one hundred dollars ($100.00) per count of conviction. The payment will be by cashier's check or money order payable to the Clerk of the United States District Court, c/o District Clerk's Office, P.O. Box 61010, Houston, Texas 77208, Attention: Finance.

Fine and Reimbursement

4. Defendant understands that under the Sentencing Guidelines, the Court is permitted to order the defendant to pay a fine that is sufficient to reimburse the government for the costs of any imprisonment or term of supervised release; if any is ordered.

5. Defendant agrees that any fine or restitution imposed by the Court will be due and payable immediately, and defendant will not attempt to avoid or delay payment.

6. Defendant agrees to make complete financial disclosure by truthfully executing a sworn financial statement (Form OBD-500) prior to sentencing if she is requested to do so. In the event that the Court imposes a fine or orders the payment of restitution as part of the Defendant's sentence, the Defendant shall make complete financial disclosure by truthfully executing a sworn financial statement immediately following her sentencing.

Cooperation

7. The parties understand this agreement carries the potential for a motion for departure under Section 5K1.1 of the Sentence Guidelines. The defendant understands and agrees that whether such a motion is filed will be determined solely by the United States through the United States Attorney for the Southern District of

Texas. Should the defendant's cooperation, in the sole judgment and discretion of the United States, amount to "substantial assistance," the United States reserves the sole right to file a motion for departure pursuant to Section 5K1.1 of the Sentencing Guidelines and Policy Statement. The defendant further agrees to persist in that plea through sentencing, fully cooperate with the United States, not oppose the forfeiture of assets contemplated in paragraph eighteen (18) and nineteen (19) of this agreement. The defendant understands and agrees that the United States will request that sentencing be deferred until that cooperation is complete.

8. The defendant understands and agrees that "fully cooperate" as used herein, includes providing all information relating to any criminal activity known to defendant, including but not limited to introduction of an unapproved new drug into interstate commerce. In that regard:

(a) Defendant agrees that this plea agreement binds only the United States Attorney for the Southern District of Texas and defendant; it does not bind any other United States Attorney or any other unit of the Department of Justice;

(b) Defendant agrees to testify truthfully as a witness before a grand jury or in any other judicial or administrative proceeding when called upon to do so by the United States. Defendant further agrees to waive her Fifth Amendment privilege against self-incrimination for the purpose of this agreement;

(c) Defendant agrees to voluntarily attend any interviews and conferences as the United States may request;

(d) Defendant agrees to provide truthful, complete and accurate information and testimony and understands any false statements made by the defendant to the Grand Jury or at any court proceeding (criminal or civil), or to a government agent or attorney can and will be prosecuted under the appropriate perjury, false statement or obstruction statutes;

(e) Defendant agrees to provide to the United States all documents in her possession or under her control relating to all areas of inquiry and investigation.

(f) Should the recommended departure, if any, not meet the defendant's expectations, the defendant understands she remains bound by the terms of this agreement and cannot, for that reason alone, withdraw her plea.

Waiver of Appeal

9. Defendant is aware that Title 18, U.S.C. § 3742 affords a defendant the right to appeal the sentence imposed. The defendant agrees to waive the right to appeal the sentence imposed or the manner in which it was determined. Additionally, the defendant is aware that Title 28, U.S.C. § 2255, affords the right to contest or "collaterally attack" a conviction or sentence after the conviction or sentence has become final. The defendant waives the right to contest her conviction or sentence by means of any post-conviction proceeding.

10. In agreeing to these waivers, defendant is aware that a sentence has not yet been determined by the Court. The defendant is also aware that any estimate of the possible sentencing range under the sentencing guidelines that she may have received from her counsel, the United States or the Probation Office, is a prediction,

not a promise, did not induce her guilty plea, and is not binding on the United States, the Probation Office or the Court. The United States does not make any promise or representation concerning what sentence the defendant will receive. Defendant further understands and agrees that the United States Sentencing Guidelines are "effectively advisory" to the Court. *United States v. Booker*, 125 S.Ct. 738 (2005). Accordingly, Defendant understands that, although the Court must consult the Sentencing Guidelines and must take them into account when sentencing Defendant, the Court is not bound to follow the Sentencing Guidelines nor sentence Defendant within the calculated guideline range.

11. The Defendant understands and agrees that each and all waivers contained in the Agreement are made in exchange for the concessions made by the United States in this plea agreement. If the defendant instructs her attorney to file a notice of appeal at the time the sentence is imposed, the government will seek specific performance of these provisions.

The United States' Agreements

12. The United States agrees to each of the following:

(a) If defendant pleads guilty to Count Twelve of the criminal information and persists in that plea through sentencing, and if the Court accepts this plea agreement, the United States will move to dismiss any remaining counts of the criminal information at the time of sentencing.

(b) At the time of sentencing, the United States agrees not to oppose defendant's anticipated request to the Court and the United States Probation Office that she receive a two (2) level downward adjustment pursuant to U.S.S.G. Section 3E1.1(a) should the defendant accept responsibility as contemplated by the Sentencing Guidelines;

(c) The government will also recommend that the defendant be sentenced at the low end of the applicable guideline range.

United States' Non-Waiver of Appeal

13. The United States reserves the right to carry out its responsibilities under guidelines sentencing. Specifically, the United States reserves the right:

(a) to bring its version of the facts of this case, including its evidence file and any investigative files, to the attention of the Probation Office in connection with that office's preparation of a pre-sentence report;

(b) to set forth or dispute sentencing factors or facts material to sentencing;

(c) to seek resolution of such factors or facts in conference with defendant's counsel and the Probation Office;

(d) to file a pleading relating to these issues, in accordance with U.S.S.G. Section 6A1.2 and Title 18, U.S.C.§ 3553(a);

(e) to appeal the sentence imposed or the manner in which it was determined

Sentence Determination

14. Defendant is aware that the sentence will be imposed after consideration

of the United States Sentencing Guidelines and Policy Statements, which are only advisory, as well as the provisions of Title 18, U.S.C. § 3553(a). Defendant nonetheless acknowledges and agrees that the Court has authority to impose any sentence up to and including the statutory maximum set for the offense(s) to which Defendant pleads guilty, and that the sentence to be imposed is within the sole discretion of the sentencing judge after the Court has consulted the applicable Sentencing Guidelines. Defendant understands and agrees the parties' positions regarding the application of the Sentencing Guidelines do not bind the Court and that the sentence imposed is within the discretion of the sentencing judge. If the Court should impose any sentence up to the maximum established by statute, or should the Court order any or all of the sentences imposed to run consecutively, Defendant cannot, for that reason alone, withdraw a guilty plea, and will remain bound to fulfill all of the obligations under this plea agreement.

Rights at Trial

15. Defendant represents to the Court that she is satisfied that her attorney has rendered effective assistance. Defendant understands that by entering into this agreement, she surrenders certain rights as provided in this plea agreement. Defendant understands that the rights of a defendant include the following:

(a) If defendant persisted in a plea of not guilty to the charges, defendant would have the right to a speedy jury trial with the assistance of counsel. The trial may be conducted by a judge sitting without a jury if the defendant, the United States, and the court all agree.

(b) At a trial, the United States would be required to present witnesses and other evidence against the defendant. Defendant would have the opportunity to confront those witnesses and her attorney would be allowed to cross-examine them. In turn, the defendant could, but would not be required to, present witnesses and other evidence on her own behalf. If the witnesses for defendant would not appear voluntarily, she could require their attendance through the subpoena power of the court.

(c) At a trial, defendant could rely on a privilege against self-incrimination and decline to testify, and no inference of guilt could be drawn from such refusal to testify. However, if the defendant desired to do so, she could testify on her own behalf.

Factual Basis for Guilty Plea

16. Defendant will plead guilty because she is in fact guilty of the charges contained in Count Twelve of the Criminal Information. In pleading guilty to this Count, defendant acknowledges the facts as stated below are true, and were the case to go to trial, the government would be able to prove those facts beyond a reasonable doubt.

Factual Basis

(1) Beginning in or about April, 2009, the defendant was the owner of a company named Global Laboratories, LLC which was located at 28150 N. Alma School Parkway, Suite 103-128, Scottsdale, Arizona 85262. Global Laboratories was

an entity the mainly focused on the manufacture, sale and distribution of stem cells. Global Laboratories, LLC however, was not a facility that was approved by the Food and Drug Administration to manufacture, market or distribute biological and drug products. Stem cells are both biological and drug products under the federal Food, Drug and Cosmetic Act and the Public Health Services Act. In December, 2008, the defendant had acquired a company named Caledonia Consulting. Caledonia was a company that also focused on the manufacture, sale and distribution of stem cells. After acquiring Caledonia, the defendant changed the company name to Global Laboratories, LLC. During this same time period, the defendant was the owner of New Hope Medical Center, a medical clinic located at 8390 E. Via de Venture, Suite F-204, in Scottsdale Arizona. The defendant was often referred to as Dr. Branyon and utilized that designation although she did not have a medical license. The defendant did receive a degree in Naturopathic Medicine from the Southwest College of Naturopathic Medicines and Health Sciences located in Arizona. New Hope Medical Center focused on the treatment of auto-immune diseases, cancer and chronic diseases with the use of stem cells.

(2) The defendant later changed the clinic name from New Hope Medical Center to Branyon Intergrative Medicine. In addition, the defendant operated websites associated with the various medical clinics that discussed the use of stem

cells to treat auto-immune and chronic diseases including amyotrophic lateral sclerosis "ALS" and multiple sclerosis "MS".

(3) Sometime in April, 2009, the defendant was contacted by an individual identified as F.M. regarding the purchase of stem cells from Global Laboratories, LLC. F.M. indicated that he was a physician with Rio Valley Medical Clinic located in Brownsville, Texas and the director of stem cell research with the Instituto Politecnico Nacional School of Medicine in Mexico City, Mexico. F.M. had previously purchased stem cells from the prior owners of Caledonia Consulting, Inc. After brief negotiations with the F.M., on April 6, 2009, the defendant sold sixteen (16) vials containing stem cells derived from cord blood to the F.M. The vials were sent by UPS from Global Laboratories, LLC to F.M. in Brownsville, Texas. F.M. in turn used the stem cells in connection with medical procedures he performed on patients suffering from ALS and MS. At the time of this transaction both the defendant and F.M. were aware that the United States Food and Drug Administration (FDA) had not approved the use of stem cells in connection with the treatment of patients suffering from incurable autoimmune diseases such as ALS and MS. The FDA has approved the use of stem cells for research purposes only and under strict guidelines which require FDA approval. The stem cells were described as eight (8) Mesenchymal Vials and eight (8) Progenitor (CD34) Vials. In connection with the

sale of the stem cells, the defendant provided F.M. with a form indicating that the sale of the stem cells was for research purposes only. However, the defendant knew that F.M. would be using the stem cells to treat patients. Subsequent to the initial sale of stem cells to F.M., the defendant sold approximately one hundred eighty three (183) vials containing stem cells to F.M. on twenty seven separate occasions during the period of April 6, 2009 through February 1, 2010. The stem cells were derived from umbilical cord blood. Investigation into the activities of F.M. indicated that F.M. was not licensed to practice medicine in any state or territory of the United States and did not work at a medical facility in Brownsville, Texas or anywhere else in the United States. The defendant received approximately three hundred thousand ($300,000) for the sale of stem cells.

(4) In order to maintain and replenish Global Laboratories, LLC inventory of stem cells, the defendant began purchasing umbilical cord tissue from a birthing facility operated by A.R. in Del Rio, Texas. A.R. a licensed midwife who delivered babies at the clinic, obtained umbilical cord tissue and cord blood from new mothers after the birth of a child. A. R. would inquire if new mothers would be willing to donate their umbilical cord and cord blood tissue for research. A.R. would have new mothers execute a form indicating the tissue would be used for research. This form was provided to A. R. by the defendant. The umbilical cord tissue was however sold

to the defendant by A.R. for the purpose of creating stem cells which could be sold to F.M. The defendant began purchasing cord blood tissue from A.R. on August 18, 2009 which continued through January 2010. The cord blood and cord blood tissue was sent from Del Rio, Texas to the defendant in Scottsdale, Arizona.

(5) The defendant who had no formal training regarding the creation of stem cells, hired V.D., a medical school professor in Charleston, South Carolina, as a consultant. V.D. a research professor, would travel to Scottsdale, Arizona on occasions to review efforts of others associated with Global Laboratories, LLC in the creation of stem cells from umbilical cord tissue. V.D. would also examine and review stem cells created from cord blood while conducting research at the medical school. The defendant, on more than one occasion, sent cord blood to V.D. in South Carolina to examine and determine the viability of creating stem cells. V.D. did create viable stems which was provided to the defendant. The stems cells were created with the intention of being utilized in the treatment of individuals suffering from diseases such as ALS and MS. These stem cells were not created in any FDA approved laboratory or under any FDA guidelines.

Breach of Plea Agreement

17. If defendant should fail in any way to fulfill completely all of the

obligations under this plea agreement, the United States will be released from its obligations under the plea agreement, and the defendant's plea and sentence will stand. If at any time defendant retains, conceals or disposes of assets in violation of this plea agreement, or if defendant knowingly withholds evidence or is otherwise not completely truthful with the United States, then the United States may move the Court to set aside the guilty plea and reinstate prosecution. Any information and documents that have been disclosed by defendant, whether prior to or subsequent to this plea agreement, and all leads derived therefrom, will be used against defendant in any prosecution.

18. Whether the defendant has breached any provision of this plea agreement shall be determined solely by the United States through the United States Attorney's Office, whose judgment in that regard is final.

Forfeiture

19. This plea agreement is being entered into by the United States on the basis of defendant's express representation that she will make a full and complete disclosure of all assets over which she exercises direct or indirect control, or in which she has any financial interest. Defendant agrees to forfeit whatever interest she may have in assets related to the Introduction of an Unapproved New Drug in Interstate Commerce, including any assets that may be listed in the superseding indictment.

20. Defendant consents to any agreed order of forfeiture or judgment, and further agrees to take all steps necessary to pass clear title to forfeitable assets to the United States, including, but not limited to, surrendering of title, signing a consent decree, stipulating facts regarding the transfer of title and basis for the forfeiture, and signing any other documents necessary to effectuate such transfer. Defendant also agrees to direct any banks which have custody of defendant's assets to deliver all funds and records of such assets to the United States.

Complete Agreement

21. This written plea agreement, consisting of eighteen (18) pages, including the attached addendum of defendant and her attorney, constitutes the complete plea agreement between the United States, defendant and her counsel. No promises or representations have been made by the United States except as set forth in writing in this plea agreement. Defendant acknowledges that no threats have been made against him/her and that she is pleading guilty freely and voluntarily because she is guilty.

22. Any modification of this plea agreement must be in writing and signed

by all parties.

Filed at Houston, Texas, on August 18, 2011.

Fredda Branyon
FREDDA BRANYON
Defendant

Subscribed and sworn to before me on August 18, 2011.

DAVID BRADLEY, Clerk
UNITED STATES DISTRICT CLERK

By: ______________________
Deputy United States District Clerk

APPROVED:
JOSE ANGEL MORENO
United States Attorney

By: ______________________
SAMUEL J. LOUIS
Assistant United States Attorney
Southern District of Texas

____
CHRISTINE WHALIN
Attorney for Defendant

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
v.	§	**CRIMINAL NO. H-11-535**
FREDDA BRANYON	§	

PLEA AGREEMENT - ADDENDUM

I have fully explained to defendant her rights with respect to the pending criminal information. I have reviewed the provisions of the United States Sentencing Commission's Guidelines Manual and Policy Statements and I have fully and carefully explained to Defendant the provisions of those Guidelines which may apply in this case. I have also explained to Defendant that the Sentencing Guidelines are only advisory and the court may sentence Defendant up to the maximum allowed by statute per count of conviction. Further, I have carefully reviewed every part of this plea agreement with Defendant. To my knowledge, Defendant's decision to enter into this agreement is an informed and voluntary one.

CHRISTINE WHALIN
Attorney for Defendant

8/18/11
Date

I have consulted with my attorney and fully understand all my rights with respect to the criminal information pending against me. My attorney has fully explained and I understand all my rights with respect to the provisions of the United States Sentencing Commission's Guidelines Manual which may apply in my case. I have read and carefully reviewed every part of this plea agreement with my attorney. I understand this agreement and I voluntarily agree to its terms.

Fredda Branyon ______________________ 8-18-11 ______________________
FREDDA BRANYON Date
Defendant